CHAD A. READLER
Acting Assistant Attorney General
Civil Division
ETHAN P. DAVIS
Deputy Assistant Attorney General
JOSHUA I. WILKENFELD
Acting Director, Consumer Protection Branch
GABRIEL H. SCANNAPIECO
gabriel.h.scannapieco@usdoj.gov
United States Department of Justice
Consumer Protection Branch, Civil Division
P.O. Box 386
Washington, DC 20044
Telephone (202) 532-4665
Facsimile (202) 514-8742

Attorneys for United States

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. CUSTOMPAX, INC., a corporation, and CEDRIC P. LING, an individual, Defendant.	Case No.: 5:17-cv-5269 **COMPLAINT FOR PERMANENT INJUNCTION AND OTHER RELIEF**

Plaintiff, the UNITED STATES OF AMERICA, by and through the undersigned attorneys, respectfully alleges as follows:

1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a), to enjoin and restrain Custompax, Inc. ("Custompax" or the "firm"), a corporation, and Cedric P. Ling, an individual (collectively, "Defendants"), from violating:

A. 21 U.S.C. § 331(a), by introducing or delivering, or causing to be introduced or delivered, into interstate commerce articles of food (dietary supplements) that are adulterated within the meaning of 21 U.S.C. § 342(g)(1); and

B. 21 U.S.C. § 331(k), by causing articles of food (dietary supplements) to become adulterated within the meaning of 21 U.S.C. § 342(g)(1), while such articles are held for sale after shipment of one or more of their components in interstate commerce.

JURISDICTION AND VENUE

2. This Court has jurisdiction under 21 U.S.C. § 332(a) and 28 U.S.C. §§ 1331, 1337, and 1345, and personal jurisdiction over all parties.

3. Venue in this district is proper under 28 U.S.C. § 1391(b) and (c).

PARTIES

4. Plaintiff is the United States of America.

5. Defendant Custompax is incorporated in the state of California and is located at 40963 Encyclopedia Circle, Fremont, CA, 94538. The firm manufactures and distributes dietary supplements. The firm has been in operation since 2005. The firm currently has 26 employees. Custompax also has an office in Beijing, China.

6. Defendant Cedric P. Ling is the Chief Executive Officer, Secretary, Chief Financial Officer, and an owner of Custompax. He has ultimate authority over the firm's operations, including business strategy, final decisions on any problems with production, and product sales and distribution. Custompax's Quality Control and Quality Assurance Manager reports directly to him. During the most recent FDA inspection, which occurred from May 17-27, 2016, Mr. Ling was identified as the most responsible person at the firm.

INTRADISTRICT ASSIGNMENT

7. The conduct at issue took place in large part in Alameda County, California.

DEFENDANT'S MANUFACTURING PROCESS

8. Custompax bills itself as "the world's leader in the mass customization of dietary supplements, enabling "anyone" to create "his or her own custom-designed supplement formula[.]" (*See* http://www.custompax.com/about.html.) All of Defendants' products consist of

custom-made, non-repeat powder formulas, packed in empty capsules of plant origin.

9. Defendants do not sell their products directly to consumers. Instead, they sell their dietary supplements to two customers who have their own websites by which physicians and healthcare providers can place orders for Custompax's products. The two customers are Compounded Nutrients, located at 3002 Dow Avenue, Suite 512, Tustin, CA, 92870; and Shenzen Catic Wellness Co., located in Shenzhen, China.

10. Through these customers, individual consumers can create and order their own unique dietary supplements by selecting the type and quantity of ingredients they want the firm to manufacture into capsules. Customers can also customize the labels on the bottles and/or give their custom supplements unique names.

11. Defendants manufacture approximately 40 batches of custom dietary supplements each week using bulk powdered ingredients obtained from third-party vendors. Every batch contains a unique mix of customer-selected powdered ingredients and requires its own master manufacturing record (MMR).

DEFENDANTS DISTRIBUTE ADULTERATED DIETARY SUPPLEMENTS

12. The Act prohibits doing or causing "the introduction or delivery for introduction into interstate commerce . . . any food [including any dietary supplement] that is adulterated." 21 U.S.C. §§ 331(a), 321(ff).

13. It is also a violation of the Act to do or cause to be done an act that results in a dietary supplement being adulterated while it is held for sale after shipment of one or more of its components in interstate commerce. 21 U.S.C. §§ 331(k), 321(ff).

14. The Act defines "dietary supplement" as "a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients: a vitamin; a mineral; an herb or other botanical; an amino acid; a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract or combination of [any of them]." 21 U.S.C. § 321(ff). In addition, a dietary supplement must not be "represented for use as a conventional food or as a sole item of a meal or the diet" and must be "labeled as a dietary supplement." *Id.*

15. Many of Defendants' products fall within the Act's definition of a dietary supplement in that they contain at least one of the dietary ingredients specified in 21 U.S.C. § 321(ff) and are labeled as dietary supplements on their principal display panels as defined in 21 C.F.R. § 101.1.

16. The Act requires manufacturers of dietary supplements to operate in compliance with current good manufacturing practice regulations for dietary supplements set forth at 21 C.F.R. Part 111 ("Dietary Supplement CGMP"). 21 U.S.C. § 342(g)(1). Manufacturing according to Dietary Supplement CGMP means that the manufacturing process incorporates a set of controls in the design and production processes to ensure a quality finished product. Dietary supplements not manufactured, prepared, packed, or held in conformance with Dietary Supplement CGMP are deemed to be adulterated. 21 U.S.C. § 342(g)(1).

17. An FDA investigator most recently inspected Defendants' facility on May 17-27, 2016 (the "May 2016 inspection"). The May 2016 inspection revealed significant deviations from Dietary Supplement CGMP, including, but not limited to, the following:

A. Defendants fail to adequately establish identity specifications for each component used in the manufacture of finished dietary supplements, in violation of 21 C.F.R. § 111.70(b)(1). Defendants lack scientific evidence to show that the test methods that they use are able to verify dietary ingredients' identities;

B. Defendants fail to establish component specifications to ensure the finished product meets specifications for purity, strength, and composition, in violation of 21 C.F.R. § 111.70(b)(2). Defendants did not establish adequate specifications for the purity, strength and composition of multiple dietary ingredients used in the manufacturing of their finished dietary supplements;

C. Defendants fail to establish product specifications for the identity, purity, strength, composition of the finished batch of dietary supplement, in violation of 21 C.F.R. § 111.70(e). For example, Defendants did not understand that strength and composition were not the same specification. In addition, Defendants believed that they could determine finished product purity by determining the collective percentage of all intended components, rather than

establishing a purity specification for the finished product;

D. Defendants fail to conduct appropriate tests or examinations to determine compliance with specifications for identity, purity, strength, and composition, in violation of 21 C.F.R. § 111.75(c)(2). For example, Defendants verify purity and composition specifications by calculation of inputs as opposed to chemical analysis;

E. Defendants fail to include all the required elements of a Master Manufacturing Record (MMR), in violation of 21 C.F.R. § 111.210. For example, for several of Defendants' products, the MMRs include procedures that do not describe adequate testing methods to determine if purity, strength, and composition specifications have been met, in violation of 21 C.F.R. § 111.210(h)(2), or do not include specific corrective action plans to use when a specification is not met, in violation of 21 C.F.R. § 111.210(h)(5); and

F. Defendants fail to conduct an appropriate review of product complaints to determine whether the complaint involved a failure of the dietary supplement to meet specifications, in violation of 21 C.F.R. § 111.560. Specifically, when reviewing a product complaint, Defendants did not perform a review of the specifications and testing results prior to release and distribution of the specific products, or a review of any other products manufactured around the same time as this batch. Defendants only conducted a retest of the returned sample for microbial content; they did not test any other product specifications to determine if they were the cause of the complaint.

DEFENDANTS ENGAGE IN INTERSTATE COMMERCE

18. During the most recent inspection, Custompax employees stated that Custompax distributes approximately 50% of its finished product into interstate commerce via FedEx or the United States Postal Service and exports at least 3-10% of its finished product.

19. The FDA investigator collected records during the May 2016 inspection that documented Defendants receiving raw ingredients from an out-of-state supplier in New Jersey.

PRIOR NOTICE

20. Defendants have been told that their conduct violates the law, and that continued violations could lead to regulatory action, having received five FDA Forms 483, Lists of

Inspectional Observations ("Form FDA 483") between 2011 and May 2016 and an FDA Warning Letter in March 2012.

21. An FDA inspector issued the most recent Form FDA 483 to Defendants at the close of a comprehensive, six-day inspection of the firm in May 2016. The FDA inspector discussed the observed deviations with the firm's Vice President of Operations, who stated that he would provide a copy of the Form FDA 483 and relate the discussion of each observation to Mr. Ling.

22. In addition, FDA conducted an inspection of the firm in August 2015, issuing a Form FDA 483 containing several of the same or similar violations from the most recent inspection, including: the failure to adequately establish identity specifications for each component used in the manufacture of finished dietary supplements; the failure to establish product specifications for the identity, purity, strength, composition of the finished batch of dietary supplement; the failure to verify that finished product met established specifications; failure to have instructions in the MMR for corrective action plans to use when specifications are not met; and the failure to conduct an appropriate investigation.

23. FDA also conducted an inspection in September 2014 and found many of the same violations that remained in 2015 and 2016, including: the failure to verify that finished product met established specifications; failure to ensure that meeting specific component and in-process specifications ensures that finished product specifications are met; and the failure to have instructions in the MMR for corrective action plans to use when specifications are not met.

24. FDA investigators documented the same or similar violations at inspections conducted in October 2012 and September 2011. At each of these inspections, FDA investigators discussed the violations listed in the Forms FDA 483 with the individual Defendant. Defendants promised corrections at every inspection, but have yet to adequately establish and implement such corrections.

25. Following the September 2011 inspection, FDA sent Defendants a Warning Letter dated February 8, 2012. The Warning Letter detailed the CGMP violations observed at the inspection and warned Defendants that failure to correct these violations could result in

enforcement action. Defendants responded to the Warning Letter on March 7, 2012, and promised corrections to the violations; FDA observed the same or similar violations at all following inspections.

26. Defendants made additional promises to correct their CGMP violations at a regulatory meeting with the San Francisco District Office on May 7, 2013, and in their most recent responses to the May 2016 Form FDA 483, dated July 11, 2016, and to the August 2015 inspection, dated September 21, 2015, and November 20, 2015. These repeated promises to correct have not, to date, yielded adequate corrective actions being implemented at Defendants' facility.

PRAYER

WHEREFORE, Plaintiff respectfully requests that the Court:

I. Enter a permanent injunction to prevent future violations of the FTC Act by Defendant with respect to the privacy of consumers' personal information;

A. Violating 21 U.S.C. § 331(a), by distributing adulterated dietary supplements in interstate commerce; and

B. Violating 21 U.S.C. § 331(k), by causing dietary supplements to become adulterated, while such articles are held for sale after shipment of one or more of their components in interstate commerce;

II. Permanently restrain and enjoin, under 21 U.S.C. § 332(a), Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, from manufacturing, processing, packing, labeling, holding, or distributing dietary supplements, unless and until Defendants' methods, facilities, and controls used to manufacture, process, pack, label, and hold dietary supplements are established, implemented, operated, administered, and recorded in conformity with the Act and Dietary Supplement CGMP, 21 C.F.R. Part 111, in a manner that has been found acceptable by FDA;

III. Order that FDA be authorized pursuant to this injunction to inspect Defendants' facility and all records relating to receiving, manufacturing, processing, packing, labeling,

holding, and distributing any drug or dietary supplement to ensure continuing compliance with the terms of the injunction, the costs of such inspections to be borne by Defendants at the rates prevailing at the time the inspections are accomplished; and

IV. That Plaintiff be granted judgment for its costs herein, and that this Court grant such other and further relief as it deems just and proper.

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Dated: September 12, 2017

Respectfully submitted,

FOR THE FOOD AND DRUG ADMINISTRATION:

JEFFREY DAVIS
Acting General Counsel

REBECCA K. WOOD
Chief Counsel
Food and Drug Division

ANNAMARIE KEMPIC
Deputy Chief Counsel for Litigation

TARA BOLAND
Associate Chief Counsel for Enforcement
Office of the Chief Counsel
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FOR PLAINTIFF THE UNITED STATES OF AMERICA:

CHAD A. READLER
Acting Assistant Attorney General
Civil Division

ETHAN P. DAVIS
Deputy Assistant Attorney General

JOSHUA I. WILKENFELD
Acting Director
Consumer Protection Branch

/s/ *Gabriel H Scannapieco* .

GABRIEL H. SCANNAPIECO
Trial Attorney
Consumer Protection Branch
U.S. Department of Justice
P.O. Box 386
Washington, DC 20044
(202) 532-4665
gabriel.h.scannapieco@usdoj.gov